

Consolidated Financial Results for the Fiscal Year Ended December 31, 2023 [Japanese GAAP]



Feb 14, 2024

Company name: Modalis Therapeutics Corporation

Stock exchange listing: Tokyo Stock Exchange

Code number: 4883

URL: <https://www.modalistx.com/jp/>

Representative: Haruhiko Morita, President and Representative Director

Contact: Naoki Kobayashi, CFO and Executive Officer

Phone: +81-3-6822-4584

Scheduled date of filing quarterly securities report: March 26, 2024

Scheduled date of commencing dividend payments: -

Availability of supplementary briefing material on quarterly financial results: Available

Schedule of quarterly financial results briefing session: - Scheduled (for securities analysts and institutional investors)

(Amounts of less than one million yen are rounded down.)

1. Consolidated Financial Results for the Fiscal Year Ended December 31, 2023 (January 1, 2023 to December 31, 2023)

(1) Consolidated Operating Results (% indicates changes from the previous corresponding period.)

	Operating revenue		Operating income		Ordinary income		Profit attributable to owners of parent	
Fiscal Year ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
December 31, 2023	-	(100)	(2,370)	-	(2,351)	-	(2,391)	-
December 31, 2022	40	-	(2,063)	-	(1,995)	-	(2,702)	-

(Note) Comprehensive income: Fiscal Year ended December 31, 2023:: ¥(2,400) million [- %]

Fiscal Year ended December 31, 2022:: ¥(2,691) million [- %]

	Basic earnings per share	Diluted earnings per share	Return of equity	Ordinary income to total assets	Operating income to operating revenue
Fiscal Year ended	Yen	Yen	%	%	%
December 31, 2023	(77.24)	-	(111.9)	(91.2)	-
December 31, 2022	(92.85)	-	(63.8)	(43.4)	-

(Notes)

The amount shown as “business revenue” in the consolidated statements of income has been shown as “Operating revenue” in this document.

Diluted net income per share is not shown in the above table, because net income per share was negative although there are residual shares.

(2) Consolidated Financial Position

	Total assets	Net assets	Capital adequacy ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of December 31, 2023	2,025	1,380	66.8	40.59
As of December 31, 2022	3,129	2,941	93.4	99.53

(Reference) Equity: As of December 31, 2023: ¥1,353 million

As of December 31, 2022: ¥2,922 million

(3) Cash flow

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at the end of period
	Million yen	Million yen	Million yen	Million yen
As of December 31, 2023	(2,254)	(39)	1,216	1,883

As of December 31, 2022	(1,895)	(185)	63	2,933
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2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended December 31, 2022	Yen -	Yen 0.00	Yen -	Yen 0.00	Yen 0.00
Fiscal year ending December 31, 2023 (year to date)	-	0.00	-		
Fiscal year ending December 31, 2023 (Forecast)				0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Consolidated Financial Forecast for the Fiscal Year Ending December 31, 2024 (January 1, 2024 to December 31, 2024)

The earnings forecasts for fiscal year ending December 2024 are not presented due to the difficulty of formulating reasonably accurate estimates at this time. For further details, please refer to the page on “Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information”

* Notes:

- (1) Changes in significant subsidiaries during the Fiscal Year ended December 31, 2023 (changes in specified subsidiaries resulting in changes in scope of consolidation): No
Notes on changes in significant subsidiaries during the Fiscal Year ended December 31, 2023
- (2) Accounting policies adopted specially for the preparation of quarterly consolidated financial statements: No
Notes on accounting policies adopted specially for the preparation of quarterly consolidated financial statements
- (3) Changes in accounting policies, changes in accounting estimates and retrospective restatement
 - 1) Changes in accounting policies due to the revision of accounting standards: No
 - 2) Changes in accounting policies other than 1) above: No
 - 3) Changes in accounting estimates: No
 - 4) Retrospective restatement: No
 Notes on changes in accounting policies

(4) Total number of issued shares (common shares)

1) Total number of issued shares at the end of the period (including treasury shares):

December 31, 2023: 33,355,272 shares

December 31, 2022: 29,362,500 shares

2) Total number of treasury shares at the end of the period:

December 31, 2023: 63 shares

December 31, 2022: 63 shares

3) Average number of shares during the period:

Fiscal Year ended December 31, 2023: 30,966,143 shares

Fiscal Year ended December 31, 2022: 29,107,190 shares

Notes on total number of issued shares

* These financial results are outside the scope of audit by certified public accountants or auditing firms.

* Explanation of the proper use of financial results forecast and other notes

The earnings forecast and other forward-looking statements herein are based on information available and certain assumptions judged to be reasonable as of the date of publication of this document. They do not represent a commitment from the Company that they will be achieved. Actual results may differ significantly from these forecast due to a wide range of factors. Please refer to a page4 on the attachment for matters related to the earnings forecast.

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1. Qualitative Information on Quarterly Financial Results for the Period under Review

(1) Explanation of Business Results

During the fourth quarter of the consolidated fiscal year under review, The Japanese economy is in the process of recovering from the new coronavirus infection, but the outlook remains uncertain due to instability in East Asia, including Ukraine, Israel, and the Taiwan Strait; rising inflation, including soaring raw material prices; and sharp fluctuations in exchange rates.

For the biotech industry, 2023 was a trying year, as the inflows seen in 2020 and '21 began to decline from '22 onward, and the global supply of funds was thin in '23, leading to pipeline reviews, restructuring, and layoffs across the industry.

In gene therapy, however, 2023 was a year in which many years of development to date came to fruition. Four in vivo gene therapies, including one for Duchenne muscular dystrophy, were approved, marking the first year of multiple drug approvals since the first approval in 2017.

Based on the CRISPR-GNDM[®] platform as the technological foundation, our group has been in business from its inception in 2016 to its eighth fiscal year as the world's first company to develop epigenetic editing therapy using CRISPR. While several similar companies have been established in the past few years, we believe it is noteworthy that we have focused on its potential even before its establishment, continue to take a leading global position in a major and popular field, and have advanced its development to the stage where clinical trials are in sight.

Our lead program, MDL-101, has largely resolved the technical and regulatory challenges of development, and is now just a GLP toxicology study and GMP manufacturing of the investigational drug away from submission of IND for clinical trials. We believe that MDL-101 has the potential to be the first CRISPR-based epigenome-editing therapeutic candidate to enter the clinic, and we are vigorously pursuing its development.

MDL-202 has resumed development with a new capsid after the reacquisition of the rights. We have already started pilot manufacturing and animal studies, and plan to accelerate development using the development strategy clarified in MDL-101.

We have also added MDL-207, a development candidate for Dravet syndrome, to our in-house pipeline. Dravet syndrome is a haploinsufficiency disease whose main symptom is convulsive seizures and is mainly caused by an abnormality in the SCN1A gene, which encodes a neuronal channel protein. The disease affects approximately 1 in 30,000 people, with 40,000* patients worldwide, 16,000* in the US, and about 3,000# in Japan. SCN1A is a large gene that cannot be carried by AAV, and like CRISPR-GNDM, raising gene expression of the remaining normal allele through transcriptional regulation. We believe that the therapeutic effect can be obtained by raising the gene expression of the remaining normal allele through transcriptional regulation, as CRISPR-GNDM does. (*Orphanet # JAPAN Intractable Disease Information Center)

Progress has also been made on the business development front, and we have agreed with JCR Pharma to evaluate and develop a molecule combining JCR's JBC-AAV technology and our CRISPR-GNDM technology for an undisclosed specific target in the central nervous system area. In the CNS area, delivery technology that can penetrate the blood-brain barrier is attracting attention, and the use of JCR's technology, which has a proven track record in protein delivery, in combination with a viral vector is expected to be a major breakthrough.

We are also in discussions with several companies about other partnering opportunities as the development path for MDL-101 becomes clearer, key technical challenges, including manufacturing, have been overcome,

and the remainder is mostly GMP and GLP - toxicology studies. Also, MDL-202, after reacquisition of the rights, has also completed the design and pilot manufacturing of the candidate molecules with muscle tropic capsids, we are also in discussions with several companies regarding partnering opportunities.

As a result, no operating revenue at the end of the year (¥40, 500 thousand for the last term), operating loss to ¥2,370,666 thousand (¥2,063,194 thousand), ordinary loss of ¥2,351,788 thousand (¥1,995,790 thousand), and Loss attributable to owners of parent to ¥2,391,821 thousand (¥2,702,709 thousand).

The Group consists of a single business segment of developing therapeutic agents for genetic disorders. Accordingly, the Company omits statements by segment.

(2) Explanation of Financial Position

Status of Assets, Liabilities and Net Assets

(Current Assets)

Total current assets at the end of the third quarter of the fiscal year under review decreased by ¥1,104,904 thousand from the end of the previous fiscal year to ¥1,956,323 thousand. This is mainly attributable to a decrease in cash and deposits by ¥1,049,725 thousand.

(Non-current Assets)

Total non-current assets at the end of the third quarter of the fiscal year under review increased by ¥996 thousand from the end of the previous fiscal year to ¥69,601 thousand. This is mainly attributable to an increase in investments and other assets by ¥996 thousand.

(Current Liabilities)

Total current liabilities at the end of the third quarter of the fiscal year under review increased by ¥56,261 from the end of the previous fiscal year to ¥198,101 thousand. This is mainly attributable to an increase in accrued expenses by ¥ 74,003 thousand and a decrease in Income taxes payable by ¥7,139 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the fiscal year increased by ¥400,641 thousand from the end of the previous fiscal year to ¥447,401 thousand. This is attributable to an increase in issued convertible bond by ¥412,500 thousand.

(Net Assets)

Total net assets at the end of the third quarter of the fiscal year under review decreased by ¥1,515,611 thousand from the end of the previous fiscal year to 1,380,422 thousand. This is mainly attributable to a decrease in the share capital and legal capital surplus both by ¥877,144.

(3) Explanation of Cash Flows

Cash and cash equivalents (hereinafter referred to as “cash”) at the end of the fiscal year decreased by ¥1,049,725 thousand, to ¥1,883,437 thousand. The status of each cash flow and their factors during the current consolidated fiscal year are as follows.

(Cash Flows from Operating Activities)

Net cash used in operating activities during the Fiscal Year ended December 31, 2023, amounted to ¥2,254,446 thousand (compared with that in last term, ¥1,895,773 thousand). This is mainly attributable to the Loss before income taxes and minority interests of ¥2,390,607 thousand yen.

(Cash Flows from Investing Activities)

Net cash used in investing activities during the Fiscal Year ended December 31, 2023, amounted to ¥39,699 thousand. This is mainly attributable to the Acquisition of tangible fixed assets of ¥39,699 thousand.

(Cash Flows from Financing Activities)

Net cash provided by financing activities during the Fiscal Year ended December 31, 2023, amounted to ¥1,26,451 thousand. This is mainly attributable to the Proceeds from issuance of shares upon exercise of stock acquisition rights, ¥736,119 thousand, and proceeds of ¥488,462 thousand from issuance of convertible bond-type bonds with subscription rights to shares.

(4) Explanation of Consolidated Financial Results Forecast and Other Forward-Looking Information

At present, we have seven in-house pipelines including MDL-101, our lead program that has been transplanted to an engineered AAV. Our primary goal is to bring the molecule to the clinic as fast as possible.

In parallel with the development, we are continuing discussions with several pharma and biotech companies for potential partnership, aiming to obtain license revenues. We are also continuing partnering for other pipelines while advancing research and development. However, our business performance fluctuates greatly depending on progress in the partnership, a major source of near-term revenue, and therefore, many undetermined factors affect our business performance at this point due to the nature of our business.

In addition, many undetermined factors in R&D expenses, which are the main expense item of our group, because, depending on the partnering arrangement, they may remain at our expense, or they may be partially or wholly at the partner's expense.

Therefore, we have decided not to disclose a forecast for the full year because there are too many undetermined factors to disclose a reasonable numerical value for the future. We will promptly disclose them when reasonable disclosure becomes possible based on the future progress of our business.

(5) Significant Events Regarding Going Concern Assumption

Our group is a biotech company engaged in the research and development of gene therapies. We have a plan to stabilize our business by combining an in-house development model and a partnering model, together we call a "hybrid" business model. However, research and development in the field require a large amount of capital and time to reach financial break-even takes a relatively long time compared to other industries, resulting in continuous operating losses and negative operating cash flow.

In the current fiscal year, the Company issued its first unsecured convertible bond with rights to acquire the stocks (also with a clause to revise the conversion price) and 12th warrant (with a clause to revise the exercise price) through a third-party allotment in November 2023 in order to secure funds for research and development. The said convertible bonds have a clause that allows the bondholders to demand redemption of a part or all of the remaining bonds at any time under certain conditions, and there is a risk that the bonds will be redeemed before the redemption date of the said convertible bonds.

In order to resolve this situation, the Group will focus on the development of MDL-101, which has employed an improved version of AAV and is based on the knowledge gained from the development of gene regulation therapeutics using CRISPR-GNDM[®] technology over the past eight fiscal years. Discussions and negotiations for partnering will continue in parallel with development as in the past. At the same time, the Company will continue to optimize its R&D structure and reduce costs by improving efficiency, while aiming for partnering as early as possible in the subsequent pipeline, centering on MDL-202.

On the funding side, as of the end of the current consolidated fiscal year, we had ¥1,883,437 million in cash and deposits, and through the above-mentioned efforts, we believe that we have sufficient funds to develop business activities in the next consolidated fiscal year. Furthermore, the Company has already issued the 12th series of stock acquisition rights with a clause to revise the exercise price through a third-party allotment in November 2023, and is in the process of raising funds.

In light of all the above, the Company recognizes that there are no significant uncertainties regarding the premise of a going concern.

2. Approach to the Selection of Accounting Standards

The Group has adopted Japanese GAAP in consideration of the comparability of its consolidated financial statements from period to period and between companies. The Group intends to adopt IFRS as appropriate, taking into consideration various conditions in Japan and overseas.

3. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of December 31, 2022	As of December 31, 2023
Assets		
Current assets		
Cash and deposits	2,933,162	1,883,437
Supplies	4,037	6,353
Other	87,757	66,533
Total current assets	3,061,228	1,956,323
Non-current assets		
Investments and other assets	68,605	69,601
Total non-current assets	68,605	69,601
Total assets	3,129,833	2,025,925
Liabilities		
Current liabilities		
Accounts payable	110,095	99,092
Accrued expenses	17,786	91,789
Income taxes payable	13,112	5,973
Other	845	1,246
Total current liabilities	141,840	198,101
Non-current liabilities		
Provision for share-based compensation for director	1,267	733
Provision for share-based compensation for employee	6,487	3,590
Bonds with stock acquisition right	-	412,500
Other	39,012	30,577
Total non-current liabilities	46,760	447,401
Total liabilities	188,600	645,502
Net assets		
Shareholders' equity		
Share capital	2,094,767	1,217,652
Capital surplus	3,416,502	2,539,387
Retained earnings	(2,605,346)	(2,410,273)
Treasury shares	(97)	(97)
Total shareholders' equity	2,905,825	1,346,669
Accumulated other comprehensive income		
Foreign currency translation adjustment	16,483	7,323
Total accumulated other comprehensive income	16,483	7,323
Subscription rights to shares	18,923	26,430
Total net assets	2,941,232	1,380,422
Total liabilities and net assets	3,129,833	2,025,925

(2) Quarterly Consolidated Statements of Income and Comprehensive Income

Quarterly Consolidated Statements of Income

For the Fiscal Year ended December 31

(Thousand yen)

	For the Fiscal Year ended December 31, 2022	For the Fiscal Year ended December 31,, 2023
Operating revenue	40,500	—
Operating expenses		
Research and development expenses	1,861,709	2,102,853
Selling, general and administrative expenses	241,985	267,812
Total operating expenses	2,103,694	2,370,666
Operating loss	(2,063,194)	(2,370,666)
Non-operating income		
Interest income	57	25
Foreign exchange income	76,445	39,417
Other	491	400
Total non-operating income	76,994	39,843
Non-operating expenses		
Interest expenses	4,823	4,414
Stock issuance cost	-	11,537
Amortization of stock issuance cost	3,304	4,413
Miscellaneous losses	552	-
Total non-operating expenses	910	600
Total non-operating expenses	9,590	20,966
Ordinary loss	(1,995,790)	(2,351,788)
Extraordinary profit		
Gain on reversal of advances received	285,559	-
Extraordinary income	285,559	-
Extraordinary loss		
Impairment loss	996,800	38,818
Total extraordinary loss	996,800	38,818
Loss before income taxes	(2,707,031)	(2,390,607)
Income taxes - current	1,451	1,213
Income taxes - deferred	(5,772)	—
Total income taxes	(4,321)	1,213
Loss	(2,702,709)	(2,391,821)
Loss attributable to owners of parent	(2,702,709)	(2,391,821)

Quarterly Consolidated Statements of Comprehensive Income

For the Fiscal Year ended December 31

(Thousand yen)

	For the Fiscal Year ended December 31, 2022	For the Fiscal Year ended December 31, 2023
Loss	(2,702,709)	(2,391,821)
Other comprehensive income		
Foreign currency translation adjustment	11,326	(9,160)
Total other comprehensive income	11,326	(9,160)
Comprehensive income	(2,691,382)	(2,400,981)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(2,691,382)	(2,400,981)

3) Consolidated Statements of Changes in Equity
Fiscal Year Ended December 31,2022

(Thousand yen)

	Shareholders' equity			
	Share capital	Capital surplus	Retained earnings	Treasury stock
Balance at beginning of current period	2,744,447	4,066,182	(1,266,476)	(97)
Changes of items during period				
Issuance of new shares	32,240	32,240		
Purchase of treasury stock	(681,920)	681,920		
Transfer to other capital surplus from capital stock		(1,363,840)	1,363,840	
Deficit disposition			(2,702,709)	
Profit attributable to owners of parent				
Net changes of items other than shareholders' equity				
Total changes of items during period	(649,680)	(649,680)	(1,338,869)	—
Balance at end of current period	2,094,767	3,416,502	(2,605,346)	(97)

	Shareholders' equity	Accumulated other comprehensive income		Subscription rights to shares	Total net assets
	Total shareholders' equity	Foreign currency translation adjustment	Total accumulated other comprehensive income		
Balance at beginning of current period	5,544,055	5,156	5,156	-	5,549,212
Changes of items during period					
Issuance of new shares	64,480				64,480
Transfer to other capital surplus from capital stock	—				—
Deficit disposition	—				—
Profit attributable to owners of parent	(2,702,709)				(2,702,709)
Net changes of items other than shareholders' equity		11,326	11,326	18,923	30,250
Total changes of items during period	(2,638,229)	11,326	11,326	18,923	(2,607,979)
Balance at end of current period	2,905,825	16,483	16,483	18,923	2,941,232

Fiscal Year Ended December 31,2023

(Thousand yen)

	Shareholders' equity			
	Share capital	Capital surplus	Retained earnings	Treasury stock
Balance at beginning of current period	2,094,767	3,416,502	(2,605,346)	(97)
Changes of items during period				
Issuance of new shares	416,332	416,332		
Purchase of treasury stock	(1,293,447)	1,293,447		
Transfer to other capital surplus from capital stock		(2,586,894)	2,586,894	
Deficit disposition				
Loss attributable to owners of parent			(2,391,821)	
Net changes of items other than shareholders' equity				
Total changes of items during period	(877,114)	(877,114)	195,073	-
Balance at end of current period	1,217,652	2,539,387	(2,410,273)	(97)

	Shareholders' equity	Accumulated other comprehensive income		Subscription rights to shares	Total net assets
	Total shareholders' equity	Foreign currency translation adjustment	Total accumulated other comprehensive income		
Balance at beginning of current period	2,905,825	16,483	16,483	18,923	2,941,232
Changes of items during period					
Issuance of new shares	832,664				832,664
Transfer to other capital surplus from capital stock	-				-
Deficit disposition	-				-
Profit attributable to owners of parent	(2,391,821)				(2,391,821)
Net changes of items other than shareholders' equity		(9,160)	(9,160)	7,506	(1,653)
Total changes of items during period	(1,559,156)	(9,160)	(9,160)	7,506	(1,560,810)
Balance at end of current period	1,346,669	7,323	7,323	26,430	1,380,422

(4) Consolidated Statements of Cash Flows

(Thousand yen)

	For the Fiscal Year ended December 31, 2022	For the Fiscal Year ended December 31, 2023
Cash flows from operating activities		
Loss before income taxes	(2,707,031)	(2,390,607)
Depreciation	123,675	731
Impairment loss	996,800	38,818
Increase (decrease) in provision for share-based compensation for director	271	(527)
Increase (decrease) in provision for share-based compensation for employee	1,712	(2,896)
Stock compensation expense	8,753	13,062
Interest and dividend income	(57)	(25)
Stock issuance cost	3,304	4,413
	-	11,537
Interest expense	4,823	4,414
Foreign exchange loss (income)	(52,521)	(27,860)
Loss on retirement of non-current assets	(552)	-
Gain on reversal of advances received	(285,559)	-
Increase (decrease) in accounts payable - other	21,710	(22,356)
Increase (decrease) in accrued expenses	(11,826)	71,848
Decrease (increase) in consumption taxes refund receivable	22,621	(9,557)
Other, net	(15,722)	60,135
Subtotal	(1,888,492)	(2,248,867)
Interest and dividends received	57	25
Interest expense paid	(6,128)	(4,414)
Income taxes paid	(1,210)	(1,210)
Net cash provided by (used in) operating activities	(1,895,773)	(2,254,466)
Cash flows from investing activities		
Purchase of property, plant and equipment	(197,287)	(39,699)
Proceeds for lease deposits	(939)	-
Payment of lease deposits	12,506	-
Net cash provided by (used in) investing activities	(185,719)	(39,699)
Cash flows from financing activities		
Repayments of installment payables	(6,751)	(6,604)
Proceeds from issuance of stock resulting from exercise of subscription right to shares	60,905	736,119
Proceeds from issuance of subscription right to shares	10,440	5,320
Payment from issuance of subscription right to shares	-	(6,246)
Purchase of treasury stock	-	488,462
Other, net	(910)	(600)
Net cash provided by (used in) financing activities	63,683	1,216,451
Effect of exchange rate change on cash and cash equivalents	14,778	27,989
Net increase (decrease) in cash and cash equivalents	(2,003,031)	(1,049,725)
Cash and cash equivalents at the beginning of period	4,936,193	2,933,162
Cash and cash equivalents at the end of period	2,933,162	1,883,437

(5) Notes to Consolidated Financial Statements

Notes on going concern assumption

- There is no relevant information.

(Segment Information, etc.)

Segment information is omitted because the Group is engaged in a single segment of gene therapy development business.

(Per share information)

	Fiscal Year ended December 31, 2022	Fiscal Year ended December 31, 2023
Net assets per share (Yen)	99,53	40.59
Net income per share (Yen)	(92,85)	(77.24)

NOTE 1. For the fiscal year ended December 31, 2022, and December 31, 2023, the figure is not presented as the Company recorded basic loss per share, although it had dilutive shares.

2. Net assets per share are calculated based on the following basis:

	Fiscal Year ended December 31, 2022	Fiscal Year ended December 31, 2023
Total net assets (thousands of yen)	2,941,232	1,380,422
Amounts deducted from total net assets (thousands of yen)	18,923	26,430
(share acquisition right ,thousands of yen)	(18,923)	(26,430)
Average number of common shares during the period (shares)	2,922,309	1,353,992
Number of common shares at the end of the period used for the calculation of net assets per share (shares)	29,362,437	33,355,209

3. Net loss per share are calculated based on the following basis:

	Fiscal Year ended December 31, 2022	Fiscal Year ended December 31, 2023
Net loss per share (thousands of yen)		
Loss attributable to owners of parent (thousands of yen)	(2,702,709)	(2,391,821)
Net loss related to common shares (thousands of yen)	—	—
Loss attributable to owners of parent to common shares (thousands of yen)	(2,702,709)	(2,391,821)
Average number of common shares during the period (shares)	29,107,190	30,571,143
Dilutive shares that do not have a diluting effect and thus were not included in the calculation of diluted net income per share	—	—

(Significant subsequent events)

There is no relevant information.